SECTION 5

WATER USE AND WASTEWATER CHARACTERIZATION

5.1 Introduction

The 1990 Detailed Questionnaire and the 1989 Pharmaceutical Screener Questionnaire distributed by EPA identified 304 facilities which used solvents and discharged wastewater from pharmaceutical manufacturing processes. The following information, based on questionnaire and screener responses, is presented in this section:

- 5.2 discusses water use and sources of wastewater;
- 5.3 discusses wastewater volume by type of discharge;
- 5.4 presents water conservation measures;
- 5.5 discusses sources of wastewater characterization data; and
- 5.6 discusses wastewater characterization.

5.2 Water Use and Sources of Wastewater

As described in 3.4.1, there are four types of pharmaceutical manufacturing operations: fermentation; biological and natural extraction; chemical synthesis; and mixing, compounding, or formulating. Water use and sources of wastewater for each process are described in more detail below.

5.2.1 Pharmaceutical Process Wastewater Sources

Process wastewater is defined by 40 CFR 122.2 as "any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product."

Water is used and wastewater is generated in pharmaceutical manufacturing processes as follows:

- Water of reaction: water formed during the chemical reaction.

- Process solvent: water used to transport or support the chemicals involved in the reaction process; this water is usually removed from the process through a separation stage, such as centrifugation, decantation, drying, or stripping.

- Process stream washes: water added to the carrier, spent acid, or spent base which has been separated from the reaction mixture, in order to purify the stream by washing away the impurities.

- Product washes: water added to the reaction medium to purify an intermediate or final product by washing away the impurities (this water is subsequently removed through a separation stage); or water used to wash the crude product after it has been removed from the reaction medium.

- Spent Acid/Caustic: spent acid and caustic streams, which may be primarily water, discharged from the process during the separation steps which follow the reaction step in which acid and basic reagents are used to facilitate, catalyze, or participate.

- Condensed steam: steam used as a sterilizing medium and in steam strippers for solvent recovery and wastewater treatment.

Other sources of process wastewater associated with pharmaceutical manufacturing operations include:

- Air pollution control scrubber blowdown: water or acidic or basic compounds used in air emission control scrubbers to control fumes from reaction vessels, storage tanks, incinerators, and other process equipment.

- Equipment and floor washes: water used to clean process equipment between product campaigns and during unit shutdowns and floors during general housekeeping or for spill cleanup.

- Pump seal water: direct contact water used to cool packing and lubricate pumps.

The following materials are excluded from the definition of process wastewater, because of their significant potential to upset the normal operation of biological wastewater treatment plants:

- Trimthyl silanol;
- Any active anti-microbial materials;
- Wastewater from imperfect fermentation batches; and
- Process area spills.

The following waters and wastewaters are excluded from the definition of process wastewater:

- Non-contact cooling water;
- Utility wastewaters;
- General site surface runoff;
- Groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects); and
- Other waters generated on site that are not process wastewaters.

Permitting the discharge of such waters and wastewaters must be considered separately from pharmaceutical manufacturing industry process wastewater.

Table 5-1 presents the amount of process wastewater generated daily in the pharmaceutical manufacturing industry that contains the organic pollutants of concern in the pharmaceutical manufacturing industry (see Table 6-1). Table 5-2 presents the amount of process wastewater generated daily which does not contain organic pollutants of concern. Pharmaceutical manufacturing wastewater associated directly with the manufacturing process as well as pump seal water and water from equipment washes is considered process wastewater in Tables 5-1 and 5-2. Table 5-3 presents the amount of wastewater generated daily from the air pollution control devices.

5.2.2 Other Facility Wastewater Sources

In addition to process wastewater, other types of wastewater may be generated during pharmaceutical manufacturing. This wastewater may include noncontact cooling water (used in heat exchangers), noncontact ancillary water (boiler blowdown, bottle washing), sanitary wastewater, and wastewater from other sources (stormwater runoff). Tables 5-4 through 5-7 present the amount of wastewater generated from these sources. Table 5-8 presents the total amount of wastewater generated by pharmaceutical manufacturing facilities by subcategory.

5.3 Wastewater Volume by Type of Discharge

This discusses the types of wastewater discharges which apply to the pharmaceutical manufacturing industry, the discharge status of the pharmaceutical manufacturing facilities, and presents total industry discharge flow rates by type of discharge.

5.3.1 Type of Discharge Definitions

There are three types of discharge which apply to the pharmaceutical manufacturing industry: direct, indirect, and zero discharge. Definitions for these discharge types are listed below.

Direct discharge refers to the discharge of a pollutant or pollutants directly to waters of the United States (not to a publicly owned treatment works). Facilities that directly discharge wastewaters do so under the National Pollutant Discharge Elimination System (NPDES) permit program.

Indirect discharge refers to the discharge of pollutants indirectly to waters of the United States, through publicly owned treatment works (POTWs).

Zero discharge refers to no discharge of pollutants to waters of the United States, as a result of either reuse of process water back into the product, no water use, recycle off site or within the plant in other processes, or disposal on or off site (e.g., by incineration, evaporation, or deep-well injection) that does not result in discharge to waters of the United States.

5.3.2 Discharge Status of Pharmaceutical Manufacturing Facilities

As discussed in 3.2.4, EPA received 244 responses to the Detailed Questionnaire. A breakdown of facility discharge status for facilities that responded to the Detailed Questionnaire and the 60 indirect discharging Subcategory D facilities with solvent use that were not sent a Detailed Questionnaire are presented in Table 5-9. Seven facilities changed discharge status in the time frame between the screener questionnaire and the Detailed Questionnaire. These facilities reported that they discharged wastewater in the screener questionnaire, but they reported zero discharge in the Detailed Questionnaire.

The flow rate and wastewater characterization data presented in this are representative of these 297 facilities.

5.3.3 Flow Rates by Type of Discharge

The total amount of process wastewater discharged from pharmaceutical manufacturing processes to waters of the United States in 1990 was approximately 104.2 MGD, compared to 105.5 MGD generated. Eighty-one percent of all process wastewater discharged was discharged directly to a receiving stream while 19% was discharged indirectly. Over 93% of the wastewater discharged in the pharmaceutical manufacturing industry is from facilities with fermentation and chemical synthesis operations. Table 5-10 presents the volumes of pharmaceutical process wastewater discharged by subcategory in 1990.

5.4 <u>Water Conservation Measures</u>

Water conservation measures were implemented with regard to process wastewater by 137 of the 244 respondents to the Detailed Questionnaire. Water conservation measures implemented include: careful monitoring of water use, installation of automatic monitoring and alarm systems on in-plant discharges, implementation of alternative production processes requiring less water, conversion from barometric to surface condensers, reuse of wastewater from other manufacturing processes, reuse of noncontact water as process makeup water, and treatment of contact cooling water to allow reuse. Table 5-11 presents the number of facilities which implemented these water conservation measures.

Table 5-12, based on the responses to the waste minimization of the Detailed Questionnaire, presents the number of facilities reporting a reduction in wastewater generated (expressed as a range in gal/yr) between 1989 and 1990.

5.5 Sources of Wastewater Characterization Data

3.2 described the many wastewater data collection efforts undertaken for development of these final effluent limitations guidelines and standards. Sources that produced data on raw wastewater characteristics included the Detailed Questionnaire and EPA sampling at pharmaceutical manufacturing facilities. Results of these data-gathering efforts are described in more detail below.

5.5.1 Data from the Detailed Questionnaire

The Detailed Questionnaire was used to gather raw wastewater information from pharmaceutical manufacturing facilities for conventional, priority, and nonconventional pollutants. These data are presented in 5.6.

5.5.2 EPA Pharmaceutical Manufacturers Sampling Program

To expand and augment the wastewater characterization data obtained in previous data-gathering efforts, EPA conducted sampling episodes at 13 pharmaceutical manufacturing facilities between 1986 and 1991. Through this sampling effort, EPA verified the presence of many of the conventional, priority, and nonconventional pollutants that were indicated as known or believed to be present in pharmaceutical manufacturing wastewater based on earlier data-gathering efforts.

The sampling program was designed to characterize the wastewaters from both direct and indirect dischargers. Direct dischargers selected for participation in the sampling program were those that met the following criteria:

- The facility attained better than BPT-level annual average effluent concentrations for BOD_5, COD, and TSS with its biological treatment system, and
- The facility's raw wastewater discharge contained significant amounts of volatile organic pollutants.

Indirect dischargers selected for participation in the sampling program were those that discharged significant levels of volatile organic pollutants in their wastewater and/or operated a wastewater pretreatment facility. Because EPA concentrated its sampling efforts at facilities with many pollutants and high concentrations of pollutants, the facilities selected were all Subcategory A and C facilities. 5.6 presents wastewater characterization data from these sampling episodes.

5.6 Wastewater Characterization

The pharmaceutical manufacturing industry generates process wastewaters containing a variety of pollutants. Most of this process wastewater receives some treatment, either in-plant at the process unit prior to commingling with other facility wastewaters or in an end-of-pipe wastewater treatment system. This presents wastewater characterization data for pharmaceutical manufacturing facilities. Data from the Detailed Questionnaire are presented in Sections 5.6.1 through 5.6.3 and data from EPA's sampling program are presented in 5.6.4. 5.6.5 presents a discussion of sulfide and sulfate containing compounds in pharmaceutical wastewaters.

5.6.1 Conventional Pollutants and COD

The two conventional pollutants in pharmaceutical manufacturing wastewater characterized by data from the Detailed Questionnaire are BOD_5 and TSS.

BOD_5, the quantity of oxygen used in the aerobic stabilization of wastewater streams, is the most widely used measure of general organic pollution in wastewater. This analytical determination involves measuring dissolved oxygen used by microorganisms to biodegrade organic matter, and varies with the amount of biodegradable matter that can be assimilated by biological organisms under aerobic conditions. EPA Method 405.1 is used to measure BOD_5. The nature of specific chemicals discharged into wastewater affects the BOD_5 due to the differences in susceptibility of different molecular structures to microbiological degradation. Compounds with lower susceptibility to decomposition by microorganisms or that are toxic to microorganisms tend to exhibit lower BOD_5 values than compounds that biodegrade readily. Consequently, while BOD_5 can provide a gross indication of the presence of organic pollutants, it is not a good indicator for the presence of specific toxic organic pollutants.

Total solids in wastewater is defined as the residue remaining upon evaporation at just above the boiling point. Total Suspended Solids (TSS) consist of the non-filterable residues which are retained by a glass filter and dried to a constant weight at 103-105^{o}C (as specified in EPA Method 160.2). Raw wastewater TSS content is a function of the manufacturing processes, as well as the manner in which fine solids may be removed during a processing step. The total solids are composed of matter which is settleable, in suspension or in solution, and can be organic, inorganic, or a mixture of both. Settleable portions of the suspended solids are usually removed in a primary clarifier. Finer materials are carried through the system, and in the case of an activated sludge system, become enmeshed with the biomass where they are then removed with the sludge during secondary clarification. Some manufacturing facilities may show an increase in TSS in the effluent from the treatment plant. This characteristic is usually associated with biological systems and indicates that secondary clarification may be inefficient in removing secondary solids. Treatment systems that include polishing ponds or lagoons may also exhibit this characteristic due to algae growth.

COD, a nonconventional pollutant, is also characterized in this because it is generally used with BOD_5 as a ratio to determine the amount of pollutants in the wastewater. COD is a measure of organic material in wastewater that can be oxidized as determined by subjecting the waste to a powerful chemical oxidizing agent (such as potassium dichromate or potassium permanganate) in an acidic medium. COD can be analyzed by EPA Methods 410.1 and 410.2. The COD test can show the presence of organic materials that are not readily susceptible to attack by biological microorganisms. As a result of this difference, COD values are almost invariably higher than BOD_5 values for the same sample. The COD test cannot be substituted directly for the BOD_5 test because the COD/BOD_5 ratio is extremely variable and is dependent on the specific chemical constituents in the wastewater. In addition, the COD test measures refractory organics, which the BOD_5 test does not. A COD/BOD_5 ratio for the wastewater from a single manufacturing facility with a constant product mix or from a single manufacturing process may be established. This ratio is applicable only to the wastewater from which it was derived and cannot be used to estimate the BOD_5 of another facility's wastewater. It is often established by facility personnel to monitor process and treatment plant performance with a minimum of analytical delay.

Information gathered from the 1987 COD study described in 3.2.2 indicates that pharmaceutical manufacturing wastewaters contain COD which is comprised of many organic compounds (not all of which could be identified in the study). One of the objectives of the study was to evaluate the effectiveness of biological treatment and PAC in removing toxic organic compounds, which contribute to the COD effluent concentration. In order to accomplish this objective, aquatic bioassay tests were performed on both raw wastewater and treated effluents from pilot-scale units. Acute and chronic bioassay tests were performed. The acute bioassay tests performed used the median lethal concentration (LC_{50}) as the end point of the test. The LC_{50} value is the concentration of sample which results in the death of half of the test organisms over the duration of the test. The concentration of the sample is expressed in terms of percent effluent, (*i.e.*, 50 percent effluent contains half sample and half dilution water). The chronic bioassay tests performed included the no observed effect concentration (NOEC) and the lowest observed effect concentration (LOEC). The NOEC is the highest concentration of sample which caused no statistically significant adverse effect on the observed organism. The LOEC is the lowest concentration of sample which caused an adverse effect on the organism of interest.

Table 5-13 summarizes the acute bioassay test results. These test results show the raw waste acute toxicity (LC_{50}) is greatly reduced by biological treatment.

The chronic data from both test periods indicate that the raw waste exhibited very high chronic toxicity with respect to both reproduction and survival. Table 5-14 summarizes the chronic bioassay test results.

The results of these tests show that COD is a good measurement of the organic chemical content in wastewaters and thus can be used as a surrogate measurement for the pharmaceutical industry whose wastewaters are dominated by organics. Biological treatment can greatly reduce COD concentrations from raw wastewater and therefore reduce wastewater toxicity.

Untreated wastewater and final effluent wastewater characterization of COD, BOD_5, and TSS was obtained from a table in the Detailed Questionnaire requesting 1990 long-term averages (in mg/L) and flow (in GPD). Table 5-10 presents this information by subcategory and type of discharge. Final effluent data represent the characteristics of wastewater sent to a POTW or discharged to surface water, and do not represent any one level or type of treatment.

Untreated wastewater concentrations and final effluent concentrations reported are not paired data. Low and high concentrations for BOD_5, COD, and TSS presented in Table 5-15 represent the range of values reported and are not from a single facility. The average concentration in the table was calculated by adding the concentration data available from each facility and dividing by the number of facilities.

The summary data shown in Table 5-15 do not necessarily represent only pharmaceutical manufacturing process wastewater, and as a result, for some subcategories, such as the Subcategory C only direct dischargers, the untreated and final effluent wastewater concentrations are biased low. EPA expects the untreated wastewater characteristics of both direct and indirect discharging Subcategory C only facilities to be similar. The similarity in wastewater characteristics between direct and indirect discharging facilities is shown in Table 5-15 for the Subcategory A only, Subcategory A/C (only), and Subcategory A/C (other) facilities, where raw concentrations for BOD5, COD and TSS are similar between direct and indirect dischargers for each respective subcategory.

EPA concludes that the reason for the discrepancy between the direct and indirect discharging Subcategory C only facilities is that wastwater flows and pollutant concentrations do not solely represent flows and concentrations from pharmaceutical manufacturing process wastewater. Rather, they represent flows and concentrations that may include dilution water or water from other sources. Of the eight direct discharging Subcategory C only facilities, six dilute their pharmaceutical wastewater stream, sent through wastewater treatment, with water from other sources to some degree (ranging from 22 percent to greater than 99 percent). These additional water sources may be characterized by lower BOD_5 and COD concentrations, resulting in a low bias of raw wastewater and effluent concentrations for conventional and non-conventional parameters. EPA believes the reported concentrations for Subcategory C only direct discharging facilities represent other water in addition to pharmaceutical manufacturing process wastewater.

Therefore, EPA expects the untreated wastewater pollutant concentrations from Subcategory C only direct dischargers to be similar to wastewater pollutant concentrations from Subcategory C only indirect dischargers, and has determined these concentrations warrant regulation.

5.6.2 Priority Pollutants

Priority pollutants regulated by this final rule (listed in 6.6) were reported as used by 93 pharmaceutical manufacturing facilities in their responses to the Detailed Questionnaire. According to the Detailed Questionnaire, the list of priority pollutants used contained both volatile and semivolatile compounds. The priority pollutants used in the greatest quantities are methylene chloride, toluene, and chloroform. Table 5-16 presents untreated wastewater and final effluent wastewater characterization data for these priority pollutants. Concentrations of priority pollutants in untreated wastewater were calculated from pollutant discharge load information and influent flow rates to the wastewater treatment plant. The pollutant load in untreated wastewater was calculated as the sum of the following: air emissions from wastewater prior to discharge, the pollutant load in wastewater discharged to surface water and/or the sewer, and the pollutant load degraded and/or destroyed in the treatment process. Concentrations of priority pollutants in final effluent wastewater were calculated from the pollutant load in wastewater discharged to surface water and/or the sewer and effluent flow rates from the wastewater treatment plant. Final effluent concentrations represent the concentration of priority pollutants in the wastewater sent to a POTW or discharged to surface water, and do not represent any one level or type of treatment.

The total mass of priority pollutants in untreated wastewater and final effluent was divided by the respective flow rate to calculate untreated wastewater and final effluent concentrations at each facility. Low and high concentrations presented in Table 5-16 represent the range of total concentration values from the facilities in the subcategory. Average concentrations were calculated by adding the total mass of priority pollutants from each facility with available data and dividing by the sum of the flows at these facilities. Discharge loads of specific priority pollutants are presented in 9.

5.6.3 Nonconventional Pollutants

Nonconventional pollutants regulated by this final rule (listed in 6.7) were reported as used by 225 pharmaceutical manufacturing facilities in their responses to the Detailed Questionnaire. According to the respondents, the nonconventional pollutants used in the largest quantities are methanol, ethanol, acetone, and isopropanol. Table 5-17 presents untreated wastewater and final effluent wastewater characterization data for these nonconventional pollutants.

The nonconventional pollutant COD is discussed in 5.6.1 because COD data were collected in the same manner as BOD_5 and TSS data. In addition, COD/BOD_5 ratios are used by facilities to monitor pharmaceutical manufacturing processes and treatment plant performance.

Ammonia is shown separately in Table 5-17 since it is not an organic compound and has rather distinct characteristics. Sampling data in the treatment performance database for ammonia are reported as ammonia as nitrogen (N) concentrations. Ammonia loads reported in the 1990 Detailed Questionnaire represent ammonium hydroxide load. To provide a consistent basis of comparison when examining ammonia discharge loads, the ammonium hydroxide loads were converted to ammonia as N loads, by multiplying the ammonium hydroxide load by 0.4. This multiplier accounts for the stoichiometric difference between nitrogen and ammonia and ammonium hydroxide.

In Table 5-17, concentrations of nonconventional pollutants in untreated wastewater were calculated from pollutant discharge load information and influent flow rates to the wastewater treatment plant reported in the 1990 Detailed Questionnaire. The pollutant load in untreated wastewater was calculated as the sum of the following: air emissions from wastewater prior to discharge, the pollutant load in wastewater discharged to surface water and/or the sewer, and the pollutant load degraded and/or destroyed in the treatment process. Concentrations of nonconventional pollutants in final effluent wastewater were calculated from the pollutant load in wastewater discharged to surface water and/or the sewer and effluent flow rates from the wastewater treatment plant. Final effluent concentrations represent the concentration of nonconventional pollutants in the wastewater sent to a POTW or discharged to surface water, and do not represent any one level or type of treatment.

The total mass of nonconventional pollutants in untreated wastewater and final effluent was divided by the respective flow rate to calculate untreated wastewater and final effluent concentrations at each facility. Low and high concentrations presented in Table 5-17 represent the range of concentration values from the facilities in the subcategory. Average concentrations were calculated by adding the total mass of nonconventional pollutants from each facility with available data and dividing by the sum of the flows at these facilities. Discharge loads of specific nonconventional pollutants are presented in 9.

5.6.4 Sampling Data

Table 5-18 summarizes untreated wastewater and final effluent wastewater characterization data from EPA sampling episodes. Priority and nonconventional pollutants in the table refer to pollutants proposed for regulation in Sections 6.6 and 6.7. Untreated wastewater data were collected from 11 of the 13 pharmaceutical facilities sampled. Final effluent data were collected from 8 of the 13 pharmaceutical facilities sampled. Final effluent wastewater characterization data do not represent any one level or type of treatment. Treatment performance data for specific treatment technologies are presented in 8.

Untreated wastewater concentrations and final effluent concentrations reported are not paired data. Low and high concentrations for ammonia as N, COD, nonconventional organics, and priority organics presented in Table 5-18 represent the range of values reported and are not from a single facility. The priority organic and nonconventional organic concentrations presented are the sum of the concentrations of individual organic constituents detected at the respective facilities. The average concentration was calculated by adding the concentration data available from each facility and dividing by the number of facilities. Full sets of sampling characterization data can be found in the sampling episode reports in the Record for this rulemaking.

5.6.5 Sulfide/Sulfate Containing Compounds

EPA has discussed with representatives of POTWs which receive pharmaceutical manufacturing wastewaters concerns related to sulfide/sulfate containing compounds discharged into POTW sewer systems. Sulfide and sulfate containing compounds discharged to POTW sewers are converted to hydrogen sulfide and released into the air under low pH conditions in the sewer lines or pumping stations leading to the POTW. The hydrogen sulfide that is produced has been measured at concentrations that create a worker safety concern and may also be an explosion concern. For example, EPA received comments from a POTW that documents on case of both worker health and safety problems along with corrosion problems as a result of pharmaceutical waste containing high sulfates converting to hydrogen sulfide in the collection system. Current treatment approaches that the Agency is aware of to reduce hydrogen sulfide emissions from POTW sewer lines include pH monitoring and the addition of ferrous chloride to sequester the sulfides in wastewater and also the addition of peroxide at pumping stations to oxidize hydrogen sulfide. Generation of hydrogen sulfide is a common concern related to the handling of untreated sewage. However, due to a lack of data specific to the discharge and treatment of these compounds in the pharmaceutical manufacturing industry, EPA did not further consider these pollutants in developing national standards. Specific problems related to sulfide/sulfate containing compounds discharged by pharmaceutical manufacturing facilities should be addressed on a case-by-case basis.

Table 5-1

Process Wastewater Generated Which Contains Organic Compounds

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	77.62
A and/or C Indirect	10.54
B and/or D Direct	0.15
B and/or D Indirect	3.12
Total	**91.43**

Table 5-2

Process Wastewater Generated Which Does Not Contain Organic Compounds

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	5.45
A and/or C Indirect	5.03
B and/or D Direct	1.29
B and/or D Indirect	2.31
Total	**14.08**

Table 5-3

Wastewater Resulting From Air Pollution Control

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	1.85
A and/or C Indirect	2.14
B and/or D Direct	0.01
B and/or D Indirect	0.33
Total	**4.33**

Table 5-4

Wastewater Resulting From Noncontact Cooling Water

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	55.71
A and/or C Indirect	42.36
B and/or D Direct	10.72
B and/or D Indirect	4.99
Total	**113.78**

Table 5-5

Wastewater Resulting From Noncontact Ancillary Water

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	16.72
A and/or C Indirect	4.24
B and/or D Direct	0.83
B and/or D Indirect	2.24
Total	**24.03**

Table 5-6

Sanitary Wastewater

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	1.10
A and/or C Indirect	4.46
B and/or D Direct	0.77
B and/or D Indirect	2.96
Total	**9.29**

Table 5-7

Wastewater From Other Sources

Subcategory and Discharge Mode	Average Quantity Generated (MGD)
A and/or C Direct	3.22
A and/or C Indirect	2.44
B and/or D Direct	0.48
B and/or D Indirect	3.34
Total	**9.48**

Table 5-8

Total Amount of Wastewater Generated from Pharmaceutical Manufacturing Facilities

Subcategory and Discharge Mode	Total Quantity Generated (MGD)
A and/or C Direct	161.67
A and/or C Indirect	71.21
B and/or D Direct	14.25
B and/or D Indirect	19.29
Total	**266.42**

Table 5-9

Facility Discharge Status by Subcategory

Subcategory	Number of Direct Discharge Facilities	Number of Indirect Discharge Facilities	Number of Facilities That Have Both Direct and Indirect Discharges	Total
A/C	23	88	1	112
B/D	12	171	2	185
Total	35	259	3	297[a]

(a) Seven facilities reported zero discharge in the Detailed Questionnaire.

Table 5-10

Volume of Process Wastewater Discharged by Subcategory

Subcategory	Volume of Process Wastewater Discharged to Surface Water (MGD)	Volume of Process Wastewater Discharged to POTW (MGD)	Total Process Water Discharged (MGD)
A/C	82.78	14.77	97.55
B/D	1.44	5.21	6.65
Total	84.20	19.98	104.20

Table 5-11

Water Conservation Measures Implemented For Process Wastewater[(a)]

Water Conservation Measure	Implemented Last 5 Years	Implemented Earlier	Total Responses
Careful monitoring of water use	79	58	137
Installation of automatic monitoring and alarm systems on in-plant discharges	36	20	56
Implementation of alternative production processes requiring less water	20	6	26
Conversion from barometric to surface condensers	6	12	18
Reuse of noncontact water as process makeup water	3	6	9
Reuse of wastewater from other manufacturing processes	6	3	9
Treatment of contact cooling water to allow reuse	4	4	8

(a)Of the 244 facilities completing the Detailed Questionnaire, 137 responded that water conservation measures were implemented with regard to process wastewater.

Table 5-12

Number of Facilities Reporting a Reduction in Wastewater Generated between 1989 and 1990

Reduction in Wastewater Quantity (gal/yr)	Number of Facilities
1 - 9,999	7
10,000 - 99,999	7
100,000 - 499,999	9
500,000 - 1,000,000	0
> 1,000,000	3
Total Number of Facilities	26

Table 5-13

COD Acute Bioassay Test Results

Acute Toxicity (48 Hours) using Ceriodaphia Dubia		
	Raw Waste LC_{50}[(a)]% (COD, mg/l)	Biological Treatment Effluent LC_{50}[(a)], % (COD, mg/l)
Test Period 1	0.81 (5,032)	46 (654)
Test Period 2	1.0 (5,694)	14 (532)

(a) LC_{50} - The concentration of sample (percent wastewater) which results in the death of half of the test organisms. Reported results are average values from four sets of daily tests for each test period.

Table 5-14

COD Bioassay Test Results

Chronic Toxicity (7 days) using Ceriodaphnia Dubia					
		Test Period 1 NOEC[(a)], %	Test Period 1 LOEC[(b)], %	Test Period 2 NOEC[(a)], %	Test Period 2 LOEC[(b)], %
Raw Waste	Survival	0.39	0.66	0.5	1
	Reproduction	<0.03	0.05	<0.01	0.01
Biological Treatment Effluent	Survival	33.3	>50.0	9.0	18.5
	Reproduction	<3.0	4.0	0.75	2.0

(a)NOEC = the highest concentration of sample which caused no statistically significant adverse effect on the observed organism. Reported results are average values from up to four sets of daily tests for each test period.
(b)LOEC = The lowest concentration of sample which caused an adverse effect on the organism of interest. Reported results are average values from up to four sets of daily tests for each test period.

Table 5-15

BOD_5, COD, and TSS Concentrations in Untreated Wastewater and Final Effluent

Type of Discharge	Current Subcategory	Pollutant	Untreated Wastewater Conc. (mg/L) Low	Untreated Wastewater Conc. (mg/L) High	Untreated Wastewater Conc. (mg/L) Ave.	Final Effluent Conc. (mg/L) Low	Final Effluent Conc. (mg/L) High	Final Effluent Conc. (mg/L) Ave.	Flow (1,000 GPD) Low	Flow (1,000 GPD) High	Flow (1,000 GPD) Ave.
Direct	A only	BOD_5	3,360	5,600	4,480	66	189	128	493	1,250	872
		COD	9,100	10,900	10,000	1,400	1,700	1,550	493	1,250	872
		TSS	264	2,490	1,380	97	264	180	493	1,250	872
	C only	BOD_5	NA	812	218	0	15	8	0	344	142
		COD	NA	1,890	718	0	923	268	0	344	142
		TSS	NA	131	55	0	53	33	0	344	142
	A and C only(a)	BOD_5	22	2,620	975	8	211	90	202	73,300	21,000
		COD	216	5,280	2,410	216	834	530	202	73,300	21,000
		TSS	39	849	332	9	232	122	202	73,300	21,000
	Other(b)	BOD_5	11	9,700	2,230	8	68	35	51	2,000	1,000
		COD	123	16,500	4,050	123	679	277	51	2,000	1,000
		TSS	40	383	185	12	143	71	51	2,000	1,000
Indirect	A only(a)	BOD_5	NA	NA	2,690	300	2,690	1,500	47	786	424
		COD	NA	NA	NA	NA	NA	566	47	786	424
		TSS	NA	NA	757	757	1,560	1,160	47	786	424
	C only(a)	BOD_5	1,250	5,430	3,470	23	5,300	1,090	0	1,620	169
		COD	1,200	22,200	7,980	267	22,200	4,030	0	1,620	169
		TSS	19	1,000	265	14	2,110	254	0	1,620	169
	A and C only(a)	BOD_5	NA	1,770	885	0	1,770	885	16	2,540	1,280
		COD	NA	4,390	2,200	0	4,390	2,200	16	2,540	1,280
		TSS	NA	888	444	0	888	444	16	2,540	1,280
	Other(a,b)	BOD_5	95	11,500	2,540	0	32,800	2,400	0	7,310	494
		COD	152	19,700	4,750	282	19,700	3,030	0	7,310	494
		TSS	14	6,070	820	0	5,810	565	0	7,310	494

Table 5-15 (Continued)

Type of Discharge	Current Subcategory	Pollutant	Untreated Wastewater Conc. (mg/L)			Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
			Low	High	Ave.	Low	High	Ave.	Low	High	Ave.
Direct	B only	BOD_5	-	-	-	-	-	-	-	-	-
		COD	-	-	-	-	-	-	-	-	-
		TSS	-	-	-	-	-	-	-	-	-
	D only	BOD_5	NA	328	117	0	145	17	2	692	110
		COD	NA	1,140	271	0	1,140	123	2	692	110
		TSS	2	306	63	2	34	11	2	692	110
	B and D only	BOD_5	NA	NA	53	NA	NA	4	NA	NA	63
		COD	NA	NA	27	NA	NA	27	NA	NA	63
		TSS	NA	NA	16	NA	NA	16	NA	NA	63
Indirect	B only(a)	BOD_5	1,850	2,350	2,100	300	2,350	1,500	2	165	28
		COD	59	3,110	1,240	59	4,480	1,740	2	165	28
		TSS	81	552	250	9	552	209	2	165	28
	D only(a)	BOD_5	NA	4,650	601	0	4,950	580	0	42,600	680
		COD	NA	6,610	907	0	2,660	502	0	42,600	680
		TSS	NA	2,060	283	0	2,410	238	0	42,600	680
	B and D only(a)	BOD_5	150	2,940	800	10	307	140	1	1,050	186
		COD	184	2,600	1,070	184	413	282	1	1,050	186
		TSS	24	743	265	24	100	63	1	1,050	186

(a)Some of these facilities provided BOD_5, COD, and TSS loadings and flows by stream. The loadings and flows were summed for all streams in the facility, and the total concentration and flow were used in this average.

(b)"Other Subcategory" denotes facilities which manufacture products in the following subcategories or subcategory combinations: ABD, ACD, AD, CD, ABCD, AB, BC, ABC, and BCD.

NA - Not available.

Table 5-16

Cyanide and Total Priority Organic Pollutant Concentrations in Pharmaceutical Manufacturing Process Wastewater

Type of Discharge	Current Subcategory	Cyanide or Priority	# of Facilities Contributing Data	Untreated Wastewater Conc. (mg/L)			Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.	Low	High	Ave.
Direct	A only	C	0									
		P	0									
	C only	C	1	-	-	4,850	-	-	5	-	-	2
		P	4	0.4	404	196	0	5	2	3	1,340	389
	A and C only	C	1	-	-	1,730	-	-	0.4	-	-	3
		P	4	20	657	306	0	17	5	114	7,210	2,160
	Other(a)	C	1	-	-	38	-	-	0.2	-	-	3
		P	6	0.3	11,900	2,860	0	141	28	21	1,220	379
Indirect	A only	C	0									
		P	0									
	C only	C	1	-	-	5	-	-	0.4	-	-	1
		P	17	0.2	4,850	589	0	1,280	94	0	862	121
	A and C only	C	0									
		P	1	-	-	619	-	-	61	-	-	154
	Other(a)	C	2	229	850	539	0	1	0.5	0	30	15
		P	32	0	79,900	3,630	0	79,900	2,670	0	1,010	201
Direct	B only	P	0									
	D only	P	3	0.2	30	10	0	0	0	11	34	21
	B and D only	P	0									

Table 5-16 (Continued)

Type of Discharge	Current Subcategory	Cyanide or Priority	# of Facilities Contributing Data	Untreated Wastewater Conc. (mg/L)			Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.	Low	High	Ave.
Indirect	B only	P	1	-	-	691	-	-	0	-	-	11
	D only	P	23	0.00	31,400	1,450	0	31,400	1,380	0	278	28
	B and D only	P	2	14.65	350	182	2	15	8	13	676	345

(a)"Other subcategory" denotes facilities which manufacture products in the following subcategories or subcategory combinations: ABD, ACD, AD, CD, ABCD, AB, BC, ABC, and BCD. P - Priority organic pollutants.
C - Cyanide.
B and D facilities did not report any cyanide in their loads or waste streams.

Table 5-17

Ammonia and Total Nonconventional Organic Pollutant Concentrations in Pharmaceutical Manufacturing Process Wastewater

Type of Discharge	Current Subcategory	Ammonia or Nonconventional	# of Facilities Contributing Data	Untreated Wastewater Conc. (mg/L)			Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.	Low	High	Ave.
Direct	A only	N	0									
		A	0									
	C only	N	5	16	15,600	3,270	0.3	155	36	3	1,340	322
		A	1	-	-	91.2	-	-	15.6	-	-	1,340
	A and C only	N	4	282	7,450	3,030	0	138	35	114	7,210	2,160
		A	1	-	-	8.4	-	-	7.6	-	-	7,210
	Other(a)	N	8	114	39,500	9,930	0	432	110	21	1,220	298
		A	5	0.02	337	133	0	240	60.4	21	720	224
Indirect	A only	N	2	54	107	81	54	107	81	24	800	412
		A	1	-	-	0.02	-	-	0.02	-	-	24
	C only	N	21	0	54,100	7,530	0	20,800	2,760	0	862	99
		A	12	4	379	142	0	350	46.4	0	862	153
	A and C only	N	2	6,860	20,800	13,900	1,720	20,800	11,300	0	154	77
		A	0									
	Other(a)	N	52	0	385,000	12,900	0	366,000	10,200	0	1,010	134
		A	27	0	87,200	3,556	0	4,640	180	0	987	187
Direct	B only	N	0									
		A	0									
	D only	N	7	0	14,300	3,130	0	6,110	928	0	20	6
		A	1	-	-	0.3	-	-	0	-	-	13
	B and D only	N	1	-	-	6	-	-	6	-	-	63
		A	0									

Table 5-17 (Continued)

Type of Discharge	Current Subcategory	Ammonia or Nonconventional	# of Facilities Contributing Data	Untreated Wastewater Conc. (mg/L)			Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.	Low	High	Ave.
Indirect	B only	N	7	0	2,010	694	0	1,700	423	0	200	32
		A	1	-	-	6.4	-	-	0	-	-	1
	D only	N	54	0	492,000	12,900	0	492,000	10,600	0	309	23
		A	4	0.2	139	39.6	0	17.6	4.8	0	5	2
	B and D only	N	9	45	49,700	9,200	45	48,400	6,840	0	676	101
		A	0	-								

(a)"Other subcategory" denotes facilities which manufacture products in the following subcategories or subcategory combinations: ABD, ACD, AD, CD, ABCD, AB, BC, ABC, and BCD
A - Ammonia as N (where ammonium hydroxide x 0.4 (mg) = ammonia as N (mg))
N - Nonconventional organic pollutants

Table 5-18

Pharmaceutical Manufacturing Industry Wastewater Characterization Data Based on EPA Sampling Episodes

Type of Discharge	Sub-category	Pollutant	# of Data Points	Untreated Wastewater Conc. (mg/L)			Flow (1,000 GPD)			# of Data Points	Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.		Low	High	Ave.	Low	High	Ave.
Direct	C only	Ammonia as N	2	170	220	195	1,830	1,960	1,900	2	120	130	125	1,830	1,960	1,900
		COD	3	2,200	4,100	2,870	1,830	2,120	1,970	2	380	400	390	1,830	1,960	1,900
		Total non-conventional organics	3	18	190	104	1,960	2,120	2,070	2	0.1	0.2	0.1	1,830	1,960	1,900
		Total priority organics	6	1	12	6	1,830	2,120	2,050	3	0.04	0.2	0.1	1,830	1,960	1,920
	A and C only	Ammonia as N	20	0.5	100	24	950	32,500	4,450	24	0.5	160	58	950	50,000	12,000
		COD	17	63	10,000	3,940	950	32,500	4,320	18	63	2,200	567	950	50,000	6,850
		Total non-conventional organics	53	0.1	236	48	950	32,500	2,560	34	0.1	8	1	1,100	50,000	12,000
		Total priority organics	70	0.08	1,440	207	950	32,500	2,210	48	0.06	4	1	950	50,000	6,430
	Other(a)	Ammonia as N	6	23	49	42	920	1,120	1,030	10	1	4	3	860	1,090	1,020
		COD	6	4,800	6,500	5,450	920	1,120	1,030	11	400	550	482	860	1,210	1,040
		Total non-conventional organics	86	1,530	2,980	2,140	920	1,120	1,060	47	15	101	26	860	1,210	1,060
		Total priority organics	42	6	11	8	920	1,120	1,030	2	0.1	0.1	0.1	990	990	990

Table 5-18 (Continued)

Type of Discharge	Sub-category	Pollutant	# of Data Points	Untreated Wastewater Conc. (mg/L)			Flow (1,000 GPD)			# of Data Points	Final Effluent Conc. (mg/L)			Flow (1,000 GPD)		
				Low	High	Ave.	Low	High	Ave.		Low	High	Ave.	Low	High	Ave.
Indirect	A and C only	Ammonia as N	2	26	35	31	1,860	1,860	1,860	0	NA	NA	NA	NA	NA	NA
		COD	2	9,700	10,000	9,850	1,860	1,860	1,860	0	NA	NA	NA	NA	NA	NA
		Total non-conventional organics	2	1	2	2	1,860	1,860	1,860	0	NA	NA	NA	NA	NA	NA
		Total priority organics	4	0.06	0.6	0.4	1,860	1,860	1,860	0	NA	NA	NA	NA	NA	NA
	Other(a)	Ammonia as N	7	6	81	37	160	2,950	1,510	6	55	190	102	700	1,930	972
		COD	11	1,600	14,000	7,230	80	2,950	1,160	7	800	12,000	4,380	700	2,120	1,140
		Total non-conventional organics	22	2	1,910	412	80	2,950	1,310	9	0.1	2,160	691	700	2,120	1,360
		Total priority organics	24	8	312	62	80	2,950	1,410	13	0.2	13	5	700	2,120	1,470

(a)"Other subcategory" denotes facilities which manufacture products in the following subcategories or subcategory combinations: ABD, ACD, AD, CD, ABCD, AB, BC, ABC, and BCD.
NA - Not available.

REFERENCES

1. Memorandum: The COD of Pharmaceutical Wastewaters, from Frank Hund to the Public Record. April 1, 1988.

2. Memorandum from Alan Messing, DynCorp-Viar. April 4, 1994.